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10/736,084	12/15/2003	Joseph C. Walsh	2003P88073 US	3273

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INTELLECTUAL PROPERTY DEPARTMENT  
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT PAPER NUMBER

1623

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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### **DETAILED ACTION**

Applicant's election without traverse of Group I, claims 1-32 in the reply filed on 5/31/2006 is acknowledged. Claims 33-34 have been cancelled. In the remarks filed in response to the Election/Restriction, applicants have stated that Claim 39 has been amended to correct minor typographical error. The Examiner would like to point out that only claims 1-34 were originally presented for prosecution out of which claims 1-32 have been elected and claims 33-34 have been cancelled. There is no claim 39. An action on the merits of claims 1-32 is contained herein below.

#### ***Title***

Since the claims drawn to radiolabelled thymidine have been cancelled a new title that is indicative of the invention to which the pending claims are directed to is required.

#### ***Claim Objections***

Claims 1, 12, 21, 29 and 30 are objected to because of the following informalities: Claims 1, 21, 29 and 30 recite structures that are not big enough to see all the substitutions and atoms clearly. In claim 12 the notation FLT should be expanded at the first occurrence. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making the nucleoside as instantly claimed wherein the base is thymidine and uridine, does not reasonably provide enablement for making the nucleoside wherein the base is other than thymidine or uridine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of one of ordinary skill
- (D) The level of predictability in the art
- (E) The amount of direction provided by the inventor
- (F) The existence of working examples
- (G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

Claims 10-11 are drawn to a method preparing a precursor of a radiolabelled nucleoside. The term nucleoside is broad and is seen to include a nucleoside that has any base moiety attached to it. Claims 30-32 are drawn to nucleosides having enolate type structure wherein sulfur and nitrogen are the heteroatoms.

**The state of the prior art**

The examiner notes that the art cited by the applicants mentions compounds containing thymidine as the base moiety of the nucleoside. However, these compounds still have some structural differences and are not representative of all other bases that are encompassed by the term nucleoside and also not representative of compounds of the structure recited in claim 30 wherein X is S and N.

**The level of one of ordinary skill**

The skilled artisan in this field is that of a synthetic chemist.

**The level of predictability in the art**

In organic synthesis, especially with regard to the synthesis of nucleosides, the synthetic steps that work for one base moiety may not work for another compound with a different base on the nucleoside because of structural differences. In the instant case, the method calls for formation of enolate, which is feasible only when an –NH group is adjacent to a carbonyl group. Not all nucleosides have bases with such a structural feature for formation of the said enolate. Moreover, making compounds of the type recited in claim 30 wherein X is nitrogen or sulfur requires the formation of the corresponding enolates, which will not form when there is a carbonyl group in the same structure. On deprotonation of the nitrogen the enolate will form on the side where the carbonyl is. This will not lead to the formation of the compound as recited in claim 30 when X is nitrogen or sulfur.

**The amount of direction provided by the inventor**

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the synthesis and use of compounds as instantly claimed by the method as instantly claimed. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis making and using the said compounds.

**The existence of working examples**

The working examples set forth in the instant specification are drawn nucleosides containing thymidine. There is little enabling disclosure for compounds containing other nucleosides. Applicant has taught how to make and use only compounds containing thymidine, which is representative of uridine and is not entitled to claim all the others encompassed by the broad recitation nucleoside.

**The quantity of experimentation needed to make or use the invention based on the content of the disclosure**

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the preparation and use of compounds as instantly claimed by the method as instantly claimed. One of ordinary skill in the art would have to make these compounds and perform undue experimentation to determine that if the said steps are feasible.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 doesn't end with a period. It is unclear if the claim ends after the structure recited in step (c) or if any additional text is intended.

Claim 12 recites the notation FLT. It is not clear what applicants intend by this notation. The expansion for the said notation followed by the notation in parentheses should be recited at the first occurrence.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 4, 12 and 21 recite the broad recitation R is C1-C4 alkyl, and the claims also recite i-propyl, which is the narrower statement of the range/limitation. Claim 10 recites the broad recitation nucleoside, and the claim also recites pyrimidine, which is the narrower statement of the range/limitation.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acevedo et al (US 6,060,592).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later



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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 21 is drawn to a pyrimidine nucleoside comprising an alkoxy substituent at the 2-position, a leaving group at the 3'-position and having a protecting group at the 5' oxygen. Dependent claims 22-28 recite limitations drawn to the alkoxy group, the protecting group and leaving group. Claim 29 is drawn to a specific pyrimidine nucleoside comprising a dimethoxytrityl group at the 5' position and a methanesulfonyl group at the 3' position. Claim 30 is drawn to a pyrimidine nucleoside comprising alkoxy, thioalkyl and amino groups at the 2-position. Claims 31 and 32 define and the protecting and leaving groups.

Acevedo et al teach pyrimidine nucleosides, thymidine, in particular (col. 8, lines 20-50; col. 9, lines 5-35), wherein a variety of substitutions are present at the 5' oxygen (protecting groups) and leaving groups including mesylate (col. 7, lines 7-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make compounds as instantly claimed since the pyrimidine nucleosides with the structural features as instantly claimed are seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to make the compounds as instantly claimed because of the presence of enol structure in the pyrimidine ring can be used in place of normal nucleotides to alter the properties, which can result in selective binding (col. 10, lines 41-65).

***Conclusion***

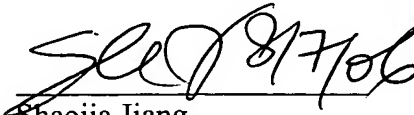
Claims 1-32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

  
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